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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/532,836	04/26/2005	Armin Breitenbach	12961/46601	8861

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EXAMINER	
VALENROD, YEVGENY	
ART UNIT	PAPER NUMBER
1621	
MAIL DATE	DELIVERY MODE
04/14/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/532,836	BREITENBACH ET AL.	
	Examiner	Art Unit	
	YEVEGENY VALENROD	1621	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 January 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *35-39 and 70-72* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *35-39 and 70-72* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *26 April 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's request for reconsideration of the finality of the rejection of the last Office action is persuasive and, therefore, the finality of that action is withdrawn.

Rejection of claims 35-39 and 70-72 under 35 USC 112 2nd paragraph is withdrawn in favor of a new rejection under the same statute.

Rejection of claims 35-39 and 70-72 under 35 USC 102(b) over Meese et al is withdrawn in favor of a new rejection over the same art.

New Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 35-39 and 70-72 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The rejected claims are directed to a compound of formula (I), however the claims comprise limitations that describe a composition.

The basis for interpreting the claims as being directed to a composition is due to presence of 3 identifiable materials in the claim language:

1) The compound of formula I, which is depicted in claim 35 as a free base.

2) Since the compound of formula I is 97% pure, there is 3% of other material that is also present.

3) The salt of the compound of formula (I), which is different from the compound of formula (I) itself.

The above described three materials being present, transforms claim 35 into a composition claim because instances where 3 different materials are present are within the scope of the claim. Also the three above described materials being present is in conflict with the claims preamble which states "A compound of the formula I". Again, the preamble states: "A compound", does not state: "A composition comprising at least 97% of compound of formula (I) or a salt thereof" (which what is being described by the claims limitations).

Examiner believes that the limitations in claim 35 are in conflict with the claims preamble. The said conflict renders claim 35 and the claims that depend therefrom indefinite, because it is not clear what the claim is directed to.

Reply to applicants' remarks

In the Appeal Brief, Applicant has argued that Examiners opinion regarding purity limitations in a compound claim are inconsistent with *In re Bergstrom,* 427 F. 2d 1394, 166 U.S.P.Q. 256 (C.C.P.A. 1970). (page 10 of the appeal brief).

Examiner disagrees with appellants' argument.

The fact pattern in *In re Bergstrom* and in the instant application is different.

Claim 23, under consideration in *In re Bergstrom* reads:

"23. 7-[3-hydroxy-2-(3hydroxy-1-octenyl)-5-oxocyclopentyl]-5-heptenoic acid, said acid being sufficiently pure to give a substantially ideal curve on partition chromatography using ethylene chloride:heptane:acetic acid:water (15:15:6:4) solvent system."

A) The above claim does not state that what being claimed is "a compound".

B) There are no clearly identifiable materials recited in the claim that would confuse one skilled in the art as to what is being claimed, a compound or a composition. In the instant case one can clearly point to the 3% of other materials and to the salt of the compound of formula I as being materials that are part of the claim limitations that are not "a compound of formula I".

C) The issue in *In re Bergstrom* was not whether a compound or a composition is being claimed, but rather is a purified compound is patentable where the compound is known to be present in a composition?

Examiner believes that the decision made in In re Bergstrom is not pertinent to the instant situation.

New Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 35-39 and 70-72 are rejected under 35 U.S.C. 102(b) as being anticipated by Meese et al (WO99/58478; already of record).

Meese et al disclose R-(+)-isobutyric acid 2-(3-diisopropylamino-1-phenylpropyl)-4-hydroxymethylphenyl ester (page 62, 3rd paragraph), (the compound of the instant claim 39). Meese discloses the compound as a free base and provides characterization of the compound in the form of: Rf value and HNMR data. The Rf value indicates that the compound was separated from the impurities on a TLC plate. The isolated compound therefore meets the limitations directed to % purity and salt content. The limitations directed to the dosing unit is inherently met by the disclosure of Meese et al. The term "dosing unit", as defined in the instant specification, is open to any amount of the active ingredient (page 16, lines 20-25 of the specification). Although the specification states that the amount sufficient for a dosing unit is a therapeutically effective amount, the specification fails to specify what amount constitutes a therapeutically effective amount. One skilled in the art would reasonably interpret that any amount of compound of formula I would meet the limitation directed to quantity of the compound present.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 35-39 and 70-72 are rejected under 35 U.S.C. 103(a) as being unpatentable over Meese et al (WO99/58478; already of record). The purpose of this rejection is to demonstrate that even if one were to accept applicant's assertion that the claims require an amount of the compound be present that is beyond what is disclosed in the art it would have been obvious to one of ordinary skill in the art at the time the invention was made to produce an amount sufficient to elicit a therapeutic effect. The rejection should not be construed as an admission that the art does not anticipate what is claimed.

Scope of prior art

Meese et al disclose R-(+)-isobutyric acid 2-(3-diisopropylamino-1-phenylpropyl)-4-hydroxymethylphenyl ester (page 62, 3rd paragraph), (the compound of the instant claim 39). Meese discloses the compound as a free base and provides characterization of the compound in the form of: Rf value and HNMR data. The Rf value indicates that the compound was separated from the impurities on a TLC plate. The isolated

compound therefore meets the limitations directed to % purity and salt content. Meese et al. also teach that the compounds of their invention can be formulated into pharmaceutical preparations and pharmacological use of the inventive compounds (page 1, first 4 lines; page 35, lines 1-5).

Ascertaining the difference between prior art and instant claims

Meese is deficient in that they do not explicitly teach an amount of purified compound sufficient for a dosing unit.

Obviousness

One skilled in the art would have found it obvious to prepare enough of R-(+)-isobutyric acid 2-(3-diisopropylamino-1-phenylpropyl)-4-hydroxymethylphenyl ester to formulate it into a dosing unit. Since Meese et al teach preparation of pharmaceutical compositions, it would be obvious to prepare enough active ingredients for a pharmaceutical preparation. Preparing sufficient quantity with the instantly claimed purity is taught by Meese. The Rf value provided by Meese on page 62, corresponds to the compounds separation on thin layer chromatography, which provides one skilled in the art with means to isolate and purify the compound of the Meese on a larger scale. Such purification can take place via column chromatography, or via Prep scale TLC, both of which are commonly utilized procedures that are well known to those skilled in the arts.

Conclusion

Claims 35-39 and 70-72 are pending.

Claims 35-39 and 70-72 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yevgeny Valenrod whose telephone number is 571-272-9049. The examiner can normally be reached on 8:30am-5:00pm M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Daniel Sullivan can be reached on 571-272-0779. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Yevgeny Valenrod/

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